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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,579

03/30/2006

Lawrence Mayer

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3865

25225 7590 11/23/2007
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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

11/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,579	Applicant(s) MAYER ET AL.	
	Examiner Gollamudi S. Kishore, Ph.D	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 33-44 is/are pending in the application.
- 4a) Of the above claim(s) 42-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election without traverse of Group I in the reply filed on 11-6 07 are acknowledged. Applicant however, cancels the originally presented claims, which were drawn to liposomes, though newly presented dependent claim recites microparticles, nanoparticles and others. The species of liposomes is deemed to be constructively elected species and therefore, is prosecuted. The originally presented claims also did not include a kit and therefore, Kit claims 43-44 are withdrawn from consideration.

Claims included in the prosecution are 33-42.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 33-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/62235 in view of WO 95/15154, Rahman (7,122,553) and in further combination with Vaage et al (International J. of cancer (1993), Mayer (6,083,530) by themselves or in combination.

WO 01 teaches a method of administration of compositions containing

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camptothecin and a pyrimidine derivative having a therapeutic synergy in the treatment of cancer. The agents are separately administered. The camptothecin derivatives include Irinotecan and others. The pyrimidine derivatives include uracil (abstract, page 1 and examples).

What is lacking in WO is the teaching of the liposomes as the delivery vehicles for the camptothecin and the pyrimidine derivative.

WO 95 discloses liposomal formulations containing FudR teaches for the treatment of hepatic metastases (abstract and page 3).

Rahman teaches liposomal compositions containing Irinotecan for increased therapeutic efficacy and reduced toxicity (abstract, col. 2, 4 and claims).

Vaage et al teach compositions containing liposomes (vehicles) and encapsulated therein two therapeutic agents, vincristine and doxorubicin. The therapeutic agents are in two separate liposome formulations. The liposome sizes are 80 nm. According to Vaage, the liposome formulations are significantly more effective than the free drugs. (Abstract, Materials and Methods and results). Vaage in addition teaches that a ~number of studies in animal models have shown that the therapeutic activities of anti-cancer drugs can be increased and prolonged and toxic effects reduced when they are encapsulated in liposomes (page 959, col. 1).

Mayer while disclosing liposomal formulations containing antineoplastic agents teaches that drug cocktails containing two or populations of liposomes

containing different antineoplastic agents can be prepared and administered for greater therapeutic efficacy (abstract and col. 9, lines 20-25).

To administer the camptothecin and pyrimidine derivatives of WO 01 in liposomes would have been obvious to one of ordinary skill in the art since the references of WO 95 and Rahman teach the increased therapeutic efficacy of these agents when encapsulated in liposomes. One of ordinary skill in the art would be motivated to encapsulate these agents in separate liposomes and administer since the reference of Vaage shows that one can administer them together but in separate liposome formulations and that of Mayer teaches that two populations of liposomes containing two different antineoplastic agents can be administered for greater therapeutic efficacy.

The references are all of record.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 33-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 5, 7-14, 20-23, 25, 27, 29-32 and 34-35 of copending Application No. 10/817,735. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending application are drawn to the same composition and therefore, instant method of delivery of the same composition for the treatment of cancer would have been obvious to one of ordinary skill in the art. Instant claim language comprising does not exclude the administration of a third agent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 33-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 and 19-21 of copending Application No. 11/304,328. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending application are drawn to the same composition; the claims in the copending application are generic with respect to the therapeutic agents and therefore, instant species are anticipated; instant method of delivery of the same composition for the treatment of cancer would have been obvious to one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 33-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20, 38-53 of copending Application No. 10/553,373. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending application are drawn to the same composition; the claims in the copending application are generic with respect to the therapeutic agents and therefore, instant species are anticipated; instant method of delivery of the same composition for the treatment of cancer would have been obvious to one of ordinary skill in the art.

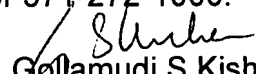
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK